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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

<u>In Vitro</u> to <u>In Vivo</u> Extrapolation for High Throughput Prioritization and Decision Making; Notice of Webinars and Public Workshop; Registration Information

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the U.S. Environmental Protection Agency (EPA) announce the workshop, "In Vitro to In Vivo Extrapolation for High Throughput Prioritization and Decision Making." Attendees at the in-person workshop and four webinar presentations leading up to the workshop will discuss the state of the science and best practices for using in vitro to in vivo extrapolation (IVIVE) in a tiered risk decision context.

DATES: Webinars: October 7, 2015, at 11:00 a.m. Eastern Daylight Time (EDT); and November 4, 2015; December 2, 2015; and January 6, 2016; at 11:00 a.m. Eastern Standard Time (EST).

Webinar Registration: Deadline is two business days prior to each webinar.

Workshop: February 17–18, 2016, from 9:00 a.m. to approximately 5:00 p.m. (EST).

Workshop Registration: Deadline is February 5, 2016 at 5:00 p.m. (EST).

ADDRESSES: Workshop Location: U.S. Environmental Protection Agency, 109 T.W. Alexander Dr., Durham, NC, 27709.

Web page: The preliminary agenda, registration, and other meeting materials will be available at http://ntp.niehs.nih.gov/go/ivive-wksp-2016.

FOR FURTHER INFORMATION CONTACT: Dr. Warren S. Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

Background: Data from high throughput <u>in vitro</u> tests are being generated for many chemicals of environmental and commercial interest, with the expectation that <u>in vitro</u> assay data could ultimately be used to predict adverse effects of chemical exposures <u>in vivo</u>. Translating values obtained from <u>in vitro</u> assays into estimates of <u>in vivo</u> outcomes is a complex process involving the use of mathematical modeling and increasingly complex test systems. The series of four webinars and in-person workshop aim to address the capabilities and limitations of IVIVE within the context of risk decision-making.

The webinar series will present the current science, and the in-person workshop will facilitate discussions that follow-up and build on information presented in the webinars. During the workshop, participants will (1) review the state of the science to form recommendations on best practices for using IVIVE in chemical screening and risk-based decision making, (2) identify areas that require additional data and/or research, and

(3) highlight examples of how best to apply IVIVE in a tiered risk decision-making strategy.

Preliminary Agenda and Other Meeting Information:

A preliminary agenda and additional information will be available at http://ntp.niehs.nih.gov/go/ivive-wksp-2016.

Meeting and Registration: This workshop is open to the public, free of charge, with attendance limited only by the space available. Registration is required to attend both the webinars and the workshop. Those persons attending the workshop should plan to participate in all four webinars. However, viewing the webinars does not require attendance at the workshop. Individuals who plan to attend the workshop must register at http://ntp.niehs.nih.gov/go/ivive-wksp-2016 by February 5, 2016. Individuals who plan to participate in the webinars must register at http://ntp.niehs.nih.gov/go/ivive-wksp-2016 two business days prior to the webinar date to ensure access. Please visit this Web page for the most current information about the webinars and workshop. For those who register, information about how to access the webinar will be emailed within two business days of each webinar.

Individuals with disabilities who need accommodation to participate in these events should contact Dr. Elizabeth Maull at phone: (919) 316-4668 or email: maull@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event. Visitor and security information for those attending the workshop can be found at http://www2.epa.gov/aboutepa/about-epas-campus-research-triangle-park-rtp-north-

carolina.

Background Information on NICEATM: NICEATM conducts data analyses,

workshops, independent validation studies, and other activities to assess new, revised,

and alternative test methods and strategies. NICEATM also provides support for the

Interagency Coordinating Committee on the Validation of Alternative Methods

(ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides

authority for ICCVAM and NICEATM in the development of alternative test methods.

Information about NICEATM and ICCVAM is found at

http://ntp.niehs.nih.gov/go/niceatm and http://ntp.niehs.nih.gov/go/iccvam, respectively.

Dated: September 14, 2015.

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